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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/747,029	12/21/2000	Ann Union	11362.0031.NPUS00	3297

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EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	16

DATE MAILED: 05/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.	Applicant(s)
09/747,029	Union et al.
Examiner	**Art Unit**
Marianne DiBrino	1644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Apr 2, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-22* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment filed 4/2/01 and response filed 2/21/02 are acknowledged and have been entered. Said response hereby places the instant application in sequence compliance.

2. **Please Note**: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 3-9, 12-15 and 18-22, drawn to a linear peptide with the primary amino acid structure consisting of SEQ ID NO: 1, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 324, 345 and 402, and Class 424, subclasses 192.1, 193.1, 185.1 and Class 435, subclass 975.

II. Claims 1, 3-9, 12-15 and 18-22, drawn to a linear peptide with the primary amino acid structure consisting of SEQ ID NO: 2, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 324, 345 and 402, and Class 424, subclasses 192.1, 193.1, 185.1 and Class 435, subclass 975.

III. Claims 1, 3-9, 12-15 and 18-22, drawn to a linear peptide with the primary amino acid structure consisting of SEQ ID NO: 3, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 324, 345 and 402, and Class 424, subclasses 192.1, 193.1, 185.1 and Class 435, subclass 975.

IV. Claims 1, 3-9, 12-15 and 18-22, drawn to a linear peptide with the primary amino acid structure consisting of SEQ ID NO: 4, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 324, 345 and 402, and Class 424, subclasses 192.1, 193.1, 185.1 and Class 435, subclass 975.

V. Claims 1, 3-9, 12-15 and 18-22, drawn to a linear peptide with the primary amino acid structure consisting of SEQ ID NO: 5, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 324, 345 and 402, and Class 424, subclasses 192.1, 193.1, 185.1 and Class 435, subclass 975.

VI. Claims 1, 3-9, 12-15 and 18-22, drawn to a linear peptide comprising the primary amino acid structure consisting of SEQ ID NO: 6, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 324, 345 and 402, and Class 424, subclasses 192.1, 193.1, 185.1 and Class 435, subclass 975.

VII. Claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure consisting of SEQ ID NO: 1, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 317, 345 and 402, and Class 435, subclass 975.

VIII. Claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure consisting of SEQ ID NO: 2, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 317, 345 and 402, and Class 435, subclass 975.

IX. Claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure consisting of SEQ ID NO: 3, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 317, 345 and 402, and Class 435, subclass 975.

X. Claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure consisting of SEQ ID NO: 4, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 317, 345 and 402, and Class 435, subclass 975.

XI. Claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure consisting of SEQ ID NO: 5, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 317, 345 and 402, and Class 435, subclass 975.

XII. Claims 1-9, 12-15 and 18-22, drawn to a cyclic peptide comprising the primary amino acid structure consisting of SEQ ID NO: 6, composition thereof and immunotoxin comprising said peptide and composition thereof, and kit comprising the said peptide, classified in Class 530, subclasses 317, 345 and 402, and Class 435, subclass 975.

XIII. Claims 10, 12-15 and 18-20, drawn to an antibody to a peptide, composition thereof, an immunotoxin comprising the said antibody and composition thereof, and a kit comprising the said antibody, classified in Class 530, subclasses 388.1 and 402 and Class 424, subclasses 1.49, 141.1, 152.1 and Class 435, subclass 975.

XIV. Claim 11, drawn to an anti-idiotypic antibody, classified in Class 530, subclass 387.2.

XV. Claim 17, drawn to a method for producing a peptide, classisfied in Class 530, subclass 345.

XVI. Claim 16, drawn to a method for producing a peptide, classisfied in Class 530, subclass 334.

4. Inventions I-XIII and XIV are different products.

The antibodies of Groups XIII and XIV and the peptides of Groups I -XII are distinct because their structures and modes of action are different.

The peptides of Groups I-VI are distinct from the peptides of Groups VII-XII are distinct because their structures are different, i.e., linear vs cyclic.

The antibody of Group XIII and the anti-idiotypic antibody of Group XIV are distinct because their structures are different, and the anti-idiotypic antibody recognizes the antibody, whereas the antibody recognizes a peptide antigen.

The peptides of Groups I-XII and XIV are distinct, one from the other because they have different primary amino acid structures and they elicit different immune responses and they bind to antibodies of different specificity.

Therefore they are patentably distinct.

5. Invention XV and Inventions I-XII are related as process of making (Invention XV) and product made (Inventions I-XII). The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the peptide can be made by solid phase or by liquid phase synthesis.

Therefore they are patentably distinct.

6. Invention XVI and Inventions I-XII are related as process of making (Invention XVI) and product made (Inventions I-XII). The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. § 806.05(f)).

In the instant case, the peptide can be made by solid phase or by liquid phase synthesis.

Therefore they are patentably distinct.

7. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-XVI is not required for any other group from Groups I-XV and Groups I-XVI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

8. **Regardless of which Group Applicant elects**, Applicant is further required to (1) elect a single disclosed species (a peptide, for example, one of the single disclosed species recited in claim 7 (such as SEQ ID NO: 7) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or

admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
May 16, 2002

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